K083602

MAR 2 6 2009

MTRE

Topic: **510K for *CritiCool system***

Establishment Name, Registration Number and Address:

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To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Ifat Oren, Regulatory Affairs

Additional electronic copy (which is an exact duplicate of the paper copy) of the submission is attached on CD

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name	System Thermal regulating
2. Classification Number:	21 CFR 870.5900
3. Common/Usual Name	Thermal regulating systems
4. Trade/Proprietary Name	CritiCool
5. Part Number of CritiCool	100-00003
6. Establishment Registration Number	9616800
7. FDA Classification	Class II
8. Product Code	DWJ
9. Reviewing Panel	Cardiovascular
10. 510 (k) marketing clearance of Medivance ArcticSun system	K071341 August 3, 2007
510(k) Marketing clearance for Allon system	K024128 – February 10, 2003 K003349 – November 13, 2000

K001546 – June 8, 2000
K992386 – March 7, 2000

Terminology

CritiCool = subject of this 510(k) submission. The CritiCool is a thermoregulation system based on water circulating via disposable Garment .

Arctic Sun Temperature Management System = the predicate device. was approved for marketing by the FDA - K071341 August 3, 2007

Allon 2001 Ver 5 = the predicate device was approved for marketing by the FDA - K024128 February 10, 2003

Device Description:

The ***CritiCool*** system consists of the following elements:

- Temperature controlled garment
- Body sensors
- Connecting flexible water pipes
- Heating/Cooling Unit

The system is operated by circulating water by a pump in a closed loop between the device and a disposable garment - CureWrap, worn by the patient. The water circulates through the thermo-regulating unit. Temperature (body) sensors are placed on the patient's skin to measure surface temperature and in the rectum, nasopharynx or esophagus to measure core temperature. The operator selects the desired patient core temperature (between 30-40°C) and the unit automatically controls it via a feedback loop. The heating / cooling unit is based on a solid-state thermo-electric device, which operates as a heat pump

The system is essentially portable, vibration free and quiet. It is designed to be connected to a standard 120 /230 VAC supply. The device is placed near the patient. Tubing is connected to both the unit and the garment (worn by the patient) and the unit is switched on. The operator selects the desired body temperature, which the unit then automatically and autonomously regulate.

CritiCool is used with CureWrap Garments with sizes equivalent to the sizes of the garments of the Allon 2001 Version 5, predicated device K024128.

Body Sensors:

The body sensors are the same sensors as those of the already cleared device with its former label of Allon 2001 Version 5. Therefore, there are no new issues of safety and effectiveness associated with these sensors

Indications for Use:
The CritiCool is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Intended Use
The Intended Use of the CritiCool monitor as indicated above is the same as the Indications for use

The following table shows all the existing CureWrap garments:

No.	Model No.	Maximum Garment Height, m	Maximum Garment Width, m	Garment Area, sq. m.
1	3521	0.698	0.602	0.347
2	3525	0.981	0.628	0.425
3	3531	1.118	0.740	0.637
4	3536	1.225	0.841	0.763
5	3541	1.390	1.054	1.089
6	3548	1.582	1.193	1.399
7	3500	2.030	1.354	2.324

Product Specifications

Listed below are the major attributes of the CritiCool compares to the predicate, ArcticSun and Allon 2001version 5.

Specifications	ArcticSun	Allon 2001 Version 5	CritiCool
FDA approval	K071341	K024128	This application

Specifications	ArcticSun	Allon 2001 Version 5	CritiCool
Control Modes	Automatic, Manual, Purge, Stop	Automatic	Automatic
Heater Capability	750 W	500W	500W
Circulating Fluid	Distilled or Sterile Water	Tap Water	Tap Water
Reservoir Capacity	5 liters	6 liters (1.6 gal)	6 liters (1.6 gal)
Heat exchanger	Jell Pads	Garment	Garment
Water flow rate (total)	0.5 - 8.0 Liter/min	1-1.2 Liter/min	1-1.2 Liter/min
Patient Probe Type	YSI 400 Series compatible	YSI 400 Series compatible	YSI 400 Series compatible
Patient Temperature Inputs	2	2 – Core temperature Surface temperature	2 – Core temperature Surface temperature
Patient Temperature Display Range	10°C to 44°C, (50°F to 111.2°F) in 0.1°C/°F steps	18.5°C to 43.9°C (65.3°F to 111.0°F) in 0.1°C/°F steps	18.5°C to 43.9°C (65.3°F to 111.0°F) in 0.1°C/°F steps
Patient Temperature Measurement Accuracy	±0.4°C 10 to 32°C ±0.2°C 32 to 38°C ±0.4°C 38 to 44°C	±0.3°C (0.4°F)	±0.3°C (0.4°F)
Patient Temperature Control Range - Automatic Mode	32°C to 38.5°C (89.6° F to 101.3°F) in 0.1°C/F increments	30°C to 40°C (86°F to 104°F) in 0.1°C/F increments	30°C to 40°C (86°F to 104°F) in 0.1°C/F increments
Water Temperature Display Range	3°C to 45°C (37.4°F to 113.0°F) in 0.1°C/F	9°C to 44°C (48.2°F to 111.2°F) in 0.1°C/F	9°C to 44°C (48.2°F to 111.2°F) in 0.1°C/F
Water Temperature Control Range Manual Mode	4°C to 42°C	N/A	N/A

Specifications	ArcticSun	Allon 2001 Version 5	CritiCool
	(39.2°F to 107.6°F) in 0.1°C/F increments		
Maximum Water Temperature (Automatic Mode)	36°C to 42°C 96.8°F to 107.6°F in 1°C/F increments	40.8°C (105.4°F)	40.8°C (105.4°F)
Minimum Water Temperature (Automatic Mode)	4°C to 25°C 39.2°F to 77°F in 1°C/F increments	13°C (55.4°F)	13°C (55.4°F)
Mains Input*	115VAC, 60 Hz, 11.0 A (nominal) 230VAC, 50 Hz, 5.5 A	230/115 VAC 500W 50/60 Hz 6.3 amp	230/115 VAC 500W 50/60 Hz 6.3 amp
Current Leakage	< 300uA	< 150uA	< 150uA
Circuit Breaker	12.0 Amp	2 X 6.3 Amp fuse	2 X 6.3 Amp fuse
Data output	Yes	Yes	Yes
Operating relative humidity range	5 - 70%	10%-100%	10%-100%
Storage relative humidity range	5 - 95% non-condensing	10%-100%	10%-100%
Operating temperature range	10°C to 27°C (50°F to 80°F)	30°C to 40°C (50-104°F)	30°C to 40°C (50-104°F)
Storage temperature range	-30°C to - 50°C (20°F to 120°F)	-40°C to 70°C (40°F to 158°F)	-40°C to 70°C (40°F to 158°F)
Height (handle down)	30" (76cm)	24.4" (62 cm)	24.4" (62 cm)
Length	22" (56cm)	24.6" (62.5 cm)	24.6" (62.5 cm)
Width	12.5" (32cm)	10.23" (26 cm)	10.23" (26 cm)
Weight when filled	116 lbs (53kg.)	86 lbs (39 Kg)	86 lbs (39 Kg)
Alarm Limits			
Water Temperature High	42.5÷C / 44÷C	42°C	42°C

Specifications	ArcticSun	Allon 2001 Version 5	CritiCool
Alarm	(108.5° F / 111.2°F)		
Water Temperature Low Alarm	3.5°C (38.3°F)	10°C	10°C
System Patient Temperature High Alarm	39.5°C (103.1°F)	38.5°C (101.3°F) or 2°C above set point	38.5°C (101.3°F) or 2°C above set point
System Patient Temperature Low Alarm	31.0°C (87.8°F)	35.5°C (95.9°F) or 0.5°C below set point	35.5°C (95.9°F) or 0.5°C below set point
Adjustable Patient Temperature High Alert	10.1°C to 44°C (50.1°F to 111.2°F)	N/A	N/A
Adjustable Patient Temperature Low Alert	10.0°C to 41.9°C50°F to 107.5°F	N/A	N/A
Patient Probe Fault Alarm Short or Open	Yes	Yes	Yes
Water flow Alert 50% of case maximum	Yes	Yes	Yes
System Water Temperature High Alarm	43.0°C/ 44°C1 (09.4°F/ 111.2°F)	42°C	42°C
System Water Temperature Low Alarm	3.0°C (37.4°F)	10C	10C
Reservoir level Alert then Alarm Low then Empty	Yes	Yes	Yes
System Self Test Alarm At power up	Yes	Yes	Yes

Materials

The material used for the CureWrap garments are :

- Water Barrier Film – Appelton MPE Grade #S6606
- Non-Woven PP (Avgol Ltd.)
- Frontal Tape FT 600

Materials were tested and proven for biocompatibility. (see part 15)

Indications for Use:
The CritiCool is a thermal regulating system, indicated for monitoring and controlling patient temperature.
Intended Use

*The Intended Use of the CritiCool monitor as indicated above is the same as the Indications For Use

Prescription Use _YES_ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

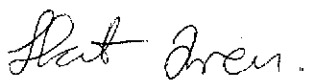
Confidentiality

MTRE Advanced Technology Ltd. considers its intent to market the CritiCool System to be confidential commercial information.

The Company, therefore, requests the FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

Signature:



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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MAR 2 6 2009

MTRE Advanced Technology Ltd.
c/o Ms. Ifat Oren
QA & Regulatory Affairs
4 Hayarden Street
Yavne, 81228, Israel

Re: K083662
CritiCool
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II
Product Code: DWJ
Dated: March 9, 2009
Received: March 11, 2009

Dear Ms. Oren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmes

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083662

Device Name: **CritiCool**

Indications For Use:

The CritiCool is a thermal regulating system, indicated for monitoring and controlling patient temperature.

*The Intended Use of the CritiCool monitor as indicated above is the same as the Indications For Use

Prescription Use __YES__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Nunes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083662